Kansas Medical Assistance Program

Drug Utilization Review Bulletin

November2004

The Kansas Medicaid Preferred Drug List (PDL)

Kansas Medicaid began implementation of a preferred drug list in December 2002. The preferred drug list was developed with the assistance of an independent clinical advisory committee of practicing physicians and pharmacists. This committee reviews clinical evidence and determines if drugs within specific therapeutic classes are equivalent in terms of safety, efficacy and clinical outcomes. Kansas Medicaid has joined with several other states to participate in the Drug Effectiveness Review Project through the Center for Evidence Based Policy. This project allows our PDL Advisory Committee to have access to the best evidence-based, clinical information on the relative effectiveness of drugs within drug classes. Making PDL decisions based upon solid clinical data provides all beneficiaries with the best value and the highest quality of care.

The current PDL includes twenty classes of drugs*:

ACE Inhibitors
Angiotensin Receptor Blockers (ARBs)
Beta-Blockers
Calcium Channel Blockers, Dihydropyridines
Calcium Channel Blockers, Nondihydropyridines
H2 Antagonists
Proton Pump Inhibitors
HMG CoA Reductase Inhibitors ("Statins")
Non-Sedating Antihistamines
Intranasal Corticosteroids
Non-Steroidal Anti-Inflammatory Drugs (NSAIDS)
Triptans
Serotonin 5-HT3 Antagonist Antiemetics
Beta-Blockers
Meglitinides
Biguanides
Alpha-Glucosidase Inhibitors
Thiazolidinediones ("Glitazones")
Insulins (Delivery Systems)
Muscle Relaxants

* Drug classes will generally be reviewed on a yearly basis.

Additional information and a complete listing of all drugs on the PDL may be found at:
http://www.srskansas.org/hcp/medicalpolicy/pharmacy/

Kansas Medicaid Preferred Drug List Committee Members:

Michael Burke, M.D., Ph.D.
Kristen Fink, PharmD
Robert Haneke, PharmD
Glenn Harte, PharmD
Vernon Mills, M.D.
Kenneth Mishler, PharmD
Brenda Schewe, M.D.
Donna Sweet, M.D.
Dennis Tietze, M.D.

To assist **Physicians** with questions pertaining to the PDL, Five Brand limit, and other Medicaid service questions, physicians may contact Kansas Medical Assistance Customer Service. Support is available from 7:30AM to 5:30PM, Monday - Friday, by calling **1-800-933-6593**.

To assist **Pharmacists** with questions pertaining to the PDL, Five Brand limit, and other pharmacy service questions, pharmacists may contact the Kansas Medical Assistance Program Help Desk. Support is available from 7AM to 7PM, seven days a week, by calling **1-866-405-5200**.

Improving Stroke Prevention in Atrial Fibrillation Patients

By Mary Peery, Pharm.D., Pharmocotherapy Specialist

Each year approximately 700,000 people in the U.S. experience a stroke, of which 70% are new cases and 30% are recurrent attacks. When stroke is considered separately from other cardiovascular diseases, it ranks as the third highest cause of death. In 2001, it accounted for greater than one out of every 15 deaths in the U.S. Stroke is also the leading cause of serious, long-term disability. About 50-70% of stroke survivors recover and are functionally independent, while 15- 30% are permanently disabled. Institutional care is necessary three months after onset in 20% of patients.[1]

Stroke is also a tremendous economic burden in our national healthcare system. It is estimated that the cost for stroke this year will be $53.6 billion, which includes both direct and indirect costs. Indirect costs include lost productivity due to morbidity and mortality. [1]

Stroke is obviously a major public health concern and is preventable, therefore efforts have been made to educate providers regarding the minimization of risk factors. In 2002, the American Heart Association (AHA) updated guidelines listing recommendations for the detection and management of established risk factors for cardiovascular disease and stroke.[2] Physicians and other healthcare providers can play a significant role in educating patients regarding these risk factors and how to manage them. Table 1 lists these risk intervention opportunities.

Table 1:
Risk Intervention for Cardiovascular Disease and Stroke[2]

- Smoking cessation
- Optimal blood pressure and diabetes control
- Improved dietary intake
- Aspirin initiation
- Cholesterol management
- Increased physical activity
- Weight management
- Chronic atrial fibrillation management

Reprints containing detailed recommendations can be obtained from the AHA.*

The Relationship between Atrial Fibrillation and Stroke

Atrial fibrillation (AF) is a major independent risk factor for stroke. About 2.4 million persons in the U.S. have AF and this number is expected to climb to more than 5.6 million by the year 2050.[3,4] AF is responsible for 15-20% of all strokes. In patients with AF, there is a 5-fold increased risk, and the risk increases with age. Not only do AF patients have an increased risk for having a stroke, but they are also twice more likely to be bedridden in comparison to patients who have a stroke secondary to other causes.[1]

Decreasing Risk in Atrial Fibrillation (AF) Patients

Although rate and rhythm control do improve the symptoms of AF, antithrombotic therapy is the mainstay for stroke prevention.[4] Aspirin and adjusted dose warfarin therapy are the primary antithrombotic treatments. Adjusted dose warfarin (INR greater than 2.0) has been shown to reduce the risk of stroke more effectively than aspirin therapy, but many patients do not benefit substantially from warfarin. In order to limit warfarin therapy to those patients where the benefit would outweigh the risks, it is important to consider the presence of other stroke risk factors.[3,5]

The overall risk of stroke in AF patients is variable depending on the presence of other associated risk factors, which include a previous history of stroke, transient ischemic attack (TIA), or systemic embolus, diabetes, coronary artery disease, left ventricular dysfunction, mitral valve disease, prosthestic heart valve, and hypertension.[3,5,6]

Difference between Major Guidelines

There are currently two major guidelines available regarding the use of antithrombotic therapy in AF. These guidelines categorize patients in risk categories based on the presence of other stroke risk factors. Tables 2 and 3 contain a summary of these guidelines.[7,8]

Overall, these guidelines are fairly similar in the treatment of most patients. The major difference is the management approach of patients who are at intermediate risk.[3] For example, warfarin or aspirin therapy is recommended by the American College of Chest Physicians (ACCP) guidelines for patients <65 years with diabetes or coronary artery disease, yet the ACC/AHA/ESC guidelines recommend warfarin therapy in patients ≥60 years with one of these diseases.[7,8]

INR target ranges are also slightly different between these guidelines. While the ACCP guidelines use the traditional range of 2.0-3.0, the ACC/AHA/ESC guidelines recommend a lower range for patients >75 years and a higher range in patients who are at extremely high risk. [7,8]

Whether a decision is made to use one or the other guideline, it is important to constantly re-evaluate the risk of individual AF patients for changes in their risk profiles. Also, for patients who fall in the less clear intermediate risk category, it is helpful to test the tolerability of warfarin therapy. Some patients maintain constant INR levels, have minimal bleeding problems, and are capable of keeping up with the frequent monitoring, while others have highly variable INR levels, frequent bleeding complications or are noncompliant with monitoring. In the case of patients who are less tolerant of warfarin therapy, their subjective input should be considered when making a therapeutic decision of warfarin or aspirin therapy.[3,6]

Table 2:
ACCP Guidelines**[7]

Risk Level	Patient Features	Therapeutic Guidelines
Low	Age ≤65 years No additional risk factors	Aspirin 325mg daily
Intermediate	Age 65-75 years Diabetes Coronary artery disease with preserved left ventricular function	Warfarin (target INR 2.5, range 2.0-3.0) or aspirin 325mg daily
High	Age >75 years Hypertension Left ventricular dysfunction More than one intermediate risk factor Mitral valve disease or prosthetic heart valve History of stroke, TIA, or systemic embolus	Warfarin (target INR 2.5, range 2.0-3.0)

**ACCP = American College of Chest Physicians

Table 3:
ACC/AHA/ESC^ Guidelines[8]

Risk Category	Patient Features	Antithrombotic Therapy
Lowest	Age <60 years No heart disease (lone AF)	Aspirin 325mg daily or no therapy
Low	Age <60 years Heart disease but no risk factors for thromboembolism (including heart failure, LV ejection fraction < 0.35, and hypertension) Age ≥60 years, no risk factors for thromboembolism	Aspirin 325mg daily
High	Age ≥60 years with diabetes mellitus or coronary artery disease	Oral anticoagulation (INR 2.0-3.0); optional addition of aspirin 81-162mg daily
	Age ≥75 years, especially women	Oral anticoagulation (INR ~ 2.0)
	Heart failure LV ejection fraction < 0.35 Thyrotoxicosis Hypertension	Oral anticoagulation (INR 2.0-3.0)
Highest	Rheumatic heart disease (mitral stenosis) Prosthetic heart valves Prior thromboembolism Persistent atrial thrombus on transesophageal echocardiography	Oral anticoagulation (INR target of at least 2.0-3.0. INR 2.5-3.5 or higher may be appropriate)

^ ACC/AHA/ESC = American College of Cardiology/American Heart Association/ European Society of Cardiology

Future of Antithrombotic Therapy

Guidelines continue to change with growing clinical evidence and may be altered with the results of emerging studies. Also, there are new generations of anticoagulants that are currently being studied. The safety of these agents is promising, and these agents do not require monitoring. Until these agents are available or new guidelines are released, healthcare providers should continue to utilize available guidelines in their current practice setting.

***AHA guidelines reprints are available by calling 1-800-242-8721 or writing the American Heart Association, Public Information, 7272 Greenville Ave., Dallas, TX 75231-4596. Ask for reprint No. 71-0226.**

1) American Heart Association. *Heart Disease and Stroke Statistics – 2004 Update*, Dallas, Tex.: American Heart Association; 2003.
2) Pearson TA, Blair SN, Daniels SR, et al. AHA guidelines for primary prevention of cardiovascular disease and stroke: 2002 update. Consensus Panel Guide to Comprehensive Risk Reduction for Adult Patients Without Coronary or Other Atherosclerotic Vascular Diseases. Circulation 2002;106:388-391.
3) Rockson SG, Albers GW. Comparing the guidelines: anticoagulation therapy to optimize stroke prevention in patients with atrial fibrillation. J AM Coll Cardiol 2004;43:929-35.
4) Bushnell CD, Matchar DB. Phamacoeconomics of atrial fibrillation and stroke prevention. Am J Manag Care 2004;10:S66-S71.
5) Hart RG, Halperin JL, Pearce LA, et al. Lessons from the stroke prevention in atrial fibrillation trials. Ann Intern Med 2003;138-:831-838.
6) Straus SE, Majumdar SR, McAlister FA. New evidence for stroke prevention. JAMA 2002;288:1388-1395.
7) Albers GW, Dalen JE, Laupacis A, Manning WJ, Petersen P, Singer DE. Antithrombotic therapy in atrial fibrillation. Chest 2001;119 Suppl 1:194S-206S.
8) Fuster V, Ryden LE, Asinger RW, et al. ACC/AHA/ESC guidelines for the management of patients with atrial fibrillation: executive summary. A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines for the Management of Patients with Atrial Fibrillation): developed in collaboration with the North American Society of Pacing and Electrophysiology. J Am Coll Cardiol 2001;38:1231-66.

FDA Public Health Advisory
October 15, 2004

Suicidality in Children and Adolescents Being Treated With Antidepressant Medications

On October 15, 2004, the Food and Drug Administration (FDA) directed manufacturers of all antidepressant drugs to revise the labeling for their products to include a boxed warning and expanded warning statements that alert health care providers to an increased risk of suicidality (suicidal thinking and behavior) in children and adolescents being treated with these agents, and to include additional information about the results of pediatric studies. FDA also informed these manufacturers that it has determined that a Patient Medication Guide (MedGuide), which will be given to patients receiving the drugs to advise them of the risk and precautions that can be taken, is appropriate for these drug products. These labeling changes are consistent with the recommendations made to the Agency at a joint meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Drugs Advisory Committee on September 13-14, 2004.

For additional information, the FDA website is listed below:

http://www.fda.gov/cder/drug/antidepressants/SSRIPHA200410.htm

Top 10 Paid Drug Products

The top 10 paid drug products in order of highest paid amount during the time period of September 2003 through August 2004 are listed below.

Drug	Claims	Paid	Paid/Rx
LANSOPRAZOLE (PREVACID) 30MG CAPSULE DR ORAL	58,060	$7,714,738	$132.88
PANTOPRAZOLE SOD SESQUIHYDRATE (PROTONIX) 40MG TABLET DR ORAL	42,734	$4,336,825	$101.48
OLANZAPINE (ZYPREXA) 10MG TABLET ORAL	9,199	$3,255,590	$353.91
QUETIAPINE FUMARATE (SEROQUEL) 200MG TABLET ORAL	9,529	$3,253,030	$341.38
OLANZAPINE (ZYPREXA) 20MG TABLET ORAL	4,871	$2,822,807	$579.51
CLOPIDOGREL BISULFATE (PLAVIX) 75MG TABLET ORAL	22,557	$2,522,011	$111.81
SERTRALINE HCL (ZOLOFT) 100MG TABLET ORAL	27,415	$2,456,606	$89.61
OLANZAPINE (ZYPREXA) 5MG TABLET ORAL	12,037	$2,452,241	$203.73
RISPERIDONE (RISPERDAL) 1MG TABLET ORAL	15,760	$2,447,307	$155.29
QUETIAPINE FUMARATE (SEROQUEL) 100MG TABLET ORAL	14,310	$2,388,075	$166.88

Kansas Drug Utilization Review Board Members

R. Kevin Bryant, M.D., C.M.D.
Michael J. Burke, M.D., Ph.D.
Dennis Grauer, Ph.D.
Linda Kroeger, ARNP
John C. Lowdermilk, R.Ph.
Barry Sarvis, R.Ph.
Brenda Schewe, M.D.
Roger D. Unruh, D.O.
Kevin Waite, PharmD

Additional information regarding the Kansas Drug Utilization Review Board may be found at:

http://www.srskansas.org/hcp/medicalpolicy/DUR/DURHome.htm.

We welcome the opportunity to discuss with you any comments or concerns you may have about this Newsletter. Please call ACS-Heritage at 1-800-745-1946 with any questions or concerns.